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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/032,239	12/21/2001	Michael Weickert	0067.00	6675
21968	7590	10/16/2003		
NEKTAR THERAPEUTICS 150 INDUSTRIAL ROAD SAN CARLOS, CA 94070			EXAMINER WANG, SHENGJUN	
			ART UNIT 1617	PAPER NUMBER
DATE MAILED: 10/16/2003				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/032,239	WEICKERT ET AL.	
	Examiner	Art Unit	
	Shengjun Wang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 31 July 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) 1-39 and 60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 40-59 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                               | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4&amp;5</u> . | 6) <input type="checkbox"/> Other: _____                                    |

### DETAILED ACTION

1. Claims 1-39 and 60 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 7.
2. Applicant's election with traverse of invention group III in Paper No. 7 is acknowledged. The traversal is on the ground(s) that all inventions are classified in the same class and subclass, and the search of the all inventions are not an undue burden. This is not found persuasive because these inventions are distinct for the reasons given above and the search required for Group III is not required for Group I or II, restriction for examination purposes as indicated is proper.
3. The requirement is still deemed proper and is therefore made FINAL.

#### *Claim Rejections 35 U.S.C. 112*

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:  

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
5. Claims 50 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
6. Claim 50 recite "neat polyene," the specification, or the claim, does not give a clear definition of "neat polyene." The claim is indefinite as to polyene encompassed thereby.

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***Rejections 35 U.S.C. 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 40-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Proffitt et al. (US 5,965,156), in view of Staniforth et al. (WO 97/03649, IDS) and Gorden et al. (US 6,077,543, IDS).

9. Proffitt et al. teaches an amphotericin liposome powder with diameters less than 2  $\mu\text{m}$ , which may be obtained through a spray drying of an acidified solution of amphotericin. The powders characterized as stable and less toxic. See, particularly, column 4, line 55 to column 7, line 35, and the claims. Further, it is well known that amphotericin B is useful for treating fungal infections. See, particularly, column 1, lines 30-45.

10. Proffitt et al. does not teach expressly a powders contains more than 30% by weight of amphotericin which is for inhalation.

11. However, Staniforth et al. teaches that powder composition for inhalation generally comprising high concentration of active ingredient, (e.g., 60% or higher by weight). See, the abstract. The optimal particle size for lung inhalation administration is 0.1  $\mu\text{m}$  to 5  $\mu\text{m}$  and leucin is added as anti-adherent material. See, particularly, the abstract. Gordon et al. teaches that hydrophobic drugs for lung delivery, such as amphotericin B are known to be made into particles less than 5  $\mu\text{m}$  in size. See, particularly, column 1, lines 52-67, column 5, line 20 to column 6, lines 62.

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Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to make a stable amphotericin powder composition for inhalation administration by drying a acidified solution of amphotericin according to Proffitt's method (without adding the other ingredients required for the liposome composition).

A person of ordinary skill in the art would have been motivated to make a stable amphotericin powder composition for inhalation administration by drying a acidified solution of amphotericin according to Proffitt's method (without adding the other ingredients required for the liposome composition) because Proffitt's method is known to provide stable amphotericin composition. Further, making a powder composition suitable for inhalation (i.e., with certain size of the particle) administration, or controlling degradation of the active ingredient during the process of making, is a matter of optimization of a result effective parameter, which is considered within the skill of the artisan, particularly in view of the fact that method of making such powders is well-known in the art (see Staniforth et al. and Gorden et al). See, In re Boesch and Slaney (CCPA) 204 USPQ 215. Further, it would have been obvious to employ a known antifungal agent for treating fungal infection patient.

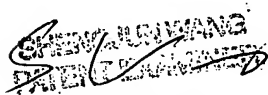
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Patent Examiner

A handwritten signature in dark ink, appearing to read 'Shengjun Wang', is written over a rectangular stamp. The stamp contains the text 'SHENGJUN WANG' and 'PATENT EXAMINER' in a bold, sans-serif font.

Shengjun Wang

October 15, 2003